



UNITED STATES PATENT AND TRADEMARK OFFICE

ck
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,787	05/04/2005	Yannis Tsouderos	SERVIER 455 PCT	4570
25666 7590 10/15/2007 THE FIRM OF HUESCHEN AND SAGE SEVENTH FLOOR, KALAMAZOO BUILDING 107 WEST MICHIGAN AVENUE KALAMAZOO, MI 49007			EXAMINER ROGERS, JUNE MARIE	
			ART UNIT 4173	PAPER NUMBER
			MAIL DATE 10/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/533,787

Applicant(s)

TSOUDEROS, YANNIS

Examiner

Juné M. Rogers

Art Unit

4173

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 4-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1sheet</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Priority

Applicant's claim of priority to PCT/FR03/0279 filed November 04, 2003 is acknowledged. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Status of Claims

Claims 1-3 are canceled; claims 4-6 are under consideration in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In independent claim 4, Applicant specify treatment of a living animal body, including human afflicted with "a condition" associated with gastro-duodenal pain. The instant specification only has support for the treatment of gastro-duodenal pain (see page 2, in the specification) not "a condition" associated

Art Unit: 4173

with gastro-duodenal pain, which is broader in scope than the treatment of gastro-duodenal pain. Additionally, the instant specification does not provide written support for the limitation of a living animal body including a human. The recitation of "a living animal body" is not support in the original claims or the instant specification. It is noted that pending claims 4-6 are not original claims. Therefore, the Examiner concludes that the treatment of "a condition" associated with gastro-duodenal pain and "a living animal body, including human" is not supported by the specification or the original claim language and thus constitutes new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention because the specification does not reasonably provide enablement for the treatment of the plethora of conditions associated with gastro-duodenal pain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Art Unit: 4173

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The instant invention relates the treatment gastro-duodenal pain by administration of the distronium salt of 2-[N,N-di(carboxymethyl)amino]-3-cyano-4- carboxymethyl-thiophene-5-carboxylic acid or hydrates thereof.

The relative skill of those in the art:

The relative skill of those in the art is high, with a typical practitioner having obtained a MD, PhD, M.S. or equivalent advanced degree.

The breadth of the claims

The instant claims are deemed very broad since the generic description of "a condition associated with gastro-duodenal pain" encompasses hundreds of conditions of different etiologies.

The predictability or lack thereof in the art and the amount of direction or guidance presented:

Art Unit: 4173

It is noted that the medical treatment art is unpredictable, requiring each embodiment to be individually assessed for viability. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses hundreds of conditions with varying etiologies. As such, the efficacy of the distrontium salt of 2-[N,N-di(carboxymethyl)amino]-3-cyano-4- carboxymethyl-thiophene-5-carboxylic acid will need to be individually evaluated in the treatment of each condition.

The specification, as filed, fails to enable one of skill in the art to use the distrontium salt of 2-[N,N-di(carboxymethyl)amino]-3-cyano-4- carboxymethyl-thiophene-5-carboxylic acid or hydrates thereof for the treatment of a condition associated with gastro-duodenal pain. For example, the Applicant provides data from clinical study. However, not a single example of the type of condition being treated is provided in the specification. Such is the case for most of Applicant's generic descriptors. One of skill in the art will recognize that in order use the distrontium salt of 2-[N,N-di(carboxymethyl)amino]-3-cyano-4- carboxymethyl-thiophene-5-carboxylic acid for the treatment of gastro-duodenal pain a substantial research and development effort is needed.

The presence or absence of working examples the quantity of experimentation necessary:

Art Unit: 4173

Applicant provides no examples of a condition associated with gastro-duodenal pain. Applicant's data is insufficient to ascertain, the patient population i.e. was this study done in human or animals and whether or not the difference reported was significant. Furthermore, the art does not recognize the treatment of gastro-duodenal pain with the distrontium salt of 2-[N,N-di(carboxymethyl)amino]-3-cyano-4-carboxymethyl-thiophene-5-carboxylic acid. This compound is typically used to treat osteoporosis. Applicant has failed to demonstrate that the distrontium salt of 2-[N,N-di(carboxymethyl)amino]-3-cyano-4-carboxymethyl-thiophene-5-carboxylic acid can be used for the treatment gastro-duodenal pain. There are no conditions shown to be treated with said compound.

The lack of working examples is a critical and crucial factor to be considered, especially in cases involving an unpredictable and undeveloped art. See MPEP § 2164. Thus, the specification fails to provide clear and convincing evidence in sufficient support of the use the distrontium salt of 2-[N,N-di(carboxymethyl)amino]-3-cyano-4-carboxymethyl-thiophene-5-carboxylic acid for treating gastro-duodenal pain. Genentech, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors as discussed above, to practice the claimed invention herein, a person of skill in the art would not be able to practice the invention commensurate in scope with the claims.

Art Unit: 4173

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 4 recites the broad recitation a living animal body, and the claim also recites including a human, which is the narrower statement of the range/limitation.

Art Unit: 4173

Conclusion

No claims allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juné M. Rogers whose telephone number is 571-270-3497. The examiner can normally be reached on M-T 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jmr

Ardin H. Marschel 10/13/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER